



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA FEDERAL EXPRESS**

Our Reference: 2939737

December 20, 2002

Xia B. Lien, Majority Stockholder  
Sunnyvale Seafood Corporation  
1651 Pomona Avenue  
San Jose, California 95110

**WARNING LETTER**

Dear Mr. Lien:

We inspected your facility located at 1651 Pomona Avenue, San Jose, California on August 21, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish, e.g., tuna-bonita, mackerel, and sardines, are adulterated, in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov). The attached handout gives information on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001, which is available on-line.

Your HACCP deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Mackerel,

Sardine, Yellowtail, Blue Runner, Yellow Fin Tuna, and Wahoo lists a monitoring procedure and frequency at the Storage critical control point that is not adequate to control histamine formation. Your listed procedure is visually checking the cooler. Measuring the temperature of the product twice a day, per your HACCP plan, is an insufficient monitoring procedure to ensure that your listed critical limit is being met and that histamine formation is being controlled.

FDA recommends maintenance of refrigerated storage coolers at 40° F or below, with continuous monitoring of the temperature, to prevent histamine formation in scombrototoxin-forming fish. Continuous monitoring can be accomplished through the use of instruments such as a time/temperature data logger. Checks on the monitoring instrument should be made at least once per day. Alternatively, if the stored fish and fishery products are maintained on ice or chemical cooling media, histamine formation can be controlled by visual checks of a representative number of containers at least twice a day to ensure that the products remain surrounded by an adequate amount of ice or cooling media.

FDA does not recommend monitoring the internal temperature of the fish, which is the monitoring procedure in your HACCP plan. Management of temperature probes in a sufficient representative number of fish to continuously monitor the internal temperature of fish that are constantly entering and exiting the cooler is a difficult task. Your critical limit should be set to reflect either the monitoring of the cooler temperature or adequacy of ice or cooling media.

Your September 17, 2002 response states that you are in the process of installing a "digital temperature reader" on your coolers and freezer. However, you describe this device as a convenient tool for viewing cooler/freezer temperature in your office, and state that reports may be printed weekly and reviewed bi-weekly. The seafood HACCP regulations require that monitoring records be reviewed within one week of preparation.

Your response also states that you have begun to monitor the temperature of product inside the cooler with random daily internal temperature checks. Random temperature checks are inadequate because they do not ensure continuous monitoring of your critical

limit. Random checks may be useful only to confirm the correct operation of the continuous monitoring instrument. If you use random checks, the checks should be conducted in a way that is meaningful and consistent with the monitoring being conducted and with the critical limit (e.g., cooler temperature versus product internal temperature). Records of the checks should also be maintained.

2. Since you chose to include corrective actions in your HACCP plan for Mackerel, Sardine, Yellowtail, Blue Runner, Yellow Fin Tuna & Wahoo, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan at the Storage CCP is not adequate to control histamine formation. Re-icing fish to achieve a temperature at or below 40°F is only a partial corrective action. Re-icing would not eliminate any histamine that formed during a period of time/temperature abuse. The affected lot should also be evaluated for its acceptability and safety based on its total time/temperature exposure. Histamine analysis of the affected lot could also be used as a corrective action measure. Finally, the written corrective action should also ensure that the cause of the critical limit deviation is corrected.

It was further noted that your corrective action plan to control histamine formation at the Receiving CCP, while acceptable as part of the plan, is not very specific, i.e., hold product for evaluation, test for histamine, and reject violative lots. For your information, the actual implementation and documentation of the corrective action when taken should be more specific regarding histamine testing and the rejection level. Where histamine testing is used as a corrective action in scenarios such as this, FDA recommends that the lot be evaluated for histamine by analyzing a minimum of 60 fish per lot (i.e., fish of common origin), or all of the fish in the lot for lots smaller than 60 fish, and reject the lot if any fish is found with histamine at or above 50 parts per million (ppm).

At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Trung Q. Lien, HACCP Coordinator. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your seafood facility operates in compliance with the Act,

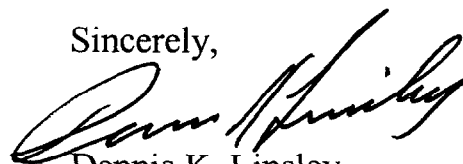
the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct the problem. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the deviations. You may wish to include in your response documentation such as copies of your HACCP plans, temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations. We acknowledge your firm's response of September 17, 2002 to the inspectional observations presented to Trung Q. Lien, HACCP Coordinator, at the close of the inspection. The corrections however, do not adequately address all the issues raised in this Warning Letter.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosures:

Form FDA 483

Handout on Fish & Fisheries Products Hazards & Controls Guidance,  
3<sup>rd</sup> edition, June 2001

cc: Hon T. Lien, President  
Trung Q. Lien, HACCP Coordinator